APPLE study (APPendicitis and Laparoscopic Evaluation) study; Multicenter prospective validation of the Laparoscopic APPendicitis (LAPP) score

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The main aim of this study is to validate the LAPP score. We hypothesize that the use of this score will lead to a 50% reduction of the total number of negative appendectomies, compared to the retrospective cohort of each participating center.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON38560

Source
ToetsingOnline

Brief title
APPLE study

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal therapeutic procedures

Synonym
Appendicitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Appendicitis, Appendix sana, Intra-operative assessment, Laparoscopy

Outcome measures

Primary outcome

To reduce the negative appendectomy rate with 50% compared with the

retrospective control group.

Secondary outcome

- The percentage of missed appendicitis should not exceed 1%.

- Cost from used materials during the operation.

- Cost form the histology review by the pathologist of a removed appendix

Study description

Background summary

During the last decade, a laparoscopic approach for a suspicion of appendicitis has become more common in surgical practice. In case the appendix looks normal the guideline of the Dutch Society of Surgeons advices not to remove it. The morbidity of a negative appendectomy is approximately 6% and it also leads to additional costs. However, until recently no criteria on how to assess the appendix during a laparoscopy has been published. In a recently performed pilot study we defined the Laparoscopic APPendectomy (LAPP) score. The LAPP score is an easy applicable score that can be used during a diagnostic laparoscopy to evaluate the appendix on the presence or absence of 5 laparoscopic criteria on appendicitis. In our prospective cohort, use of the LAPP score would have led to a positive predictive value of 99% and a negative predictive value of 100%. The goal of the current study is to validate the LAPP score in a prospective multicenter validation study. Our hypothesis is that the application of the LAPP score leads to a reduction of 50% of negative appendectomies compared with a retrospective cohort in the same centers. We have chosen to compare the

normal appendectomy rate of this prospective multicenter validation study with a retrospective control group. The control group consists of 843 patients operated in 5 centers in 2008 and 2009 with a normal appendectomy rate of 9%.

An alternative approach as a study design would be to initiate a randomized (non-blinded) control trial, in such a case the surgeon will be asked to use the LAPP score in half of the included patients and not to use it in the next patient. We feel that it is not feasible for a surgeon to use the LAPP score in one patient and not to use it in the next patient. In addition, after publication of the results of the LAPP study surgeons might already start to use the LAPP score or at least will evaluate the appendix differently than before.

Study objective

The main aim of this study is to validate the LAPP score. We hypothesize that the use of this score will lead to a 50% reduction of the total number of negative appendectomies, compared to the retrospective cohort of each participating center.

Study design

Prospective cohort design, multicenter prospective validation study in 760 patients suspected for appendicitis with an indication for diagnostic laparoscopy. We expect to fulfill the inclusion within one and half year.
This cohort will be compared with a multicenter historical cohort. Each center will be its own control group.

Intervention

Intra-operative use of the LAPP score.
The LAPP score consists of five questions regarding signs of appendicitis. Each question could be answered with 'yes' of 'no'. If all five questions are answered with no, the appendix is considered sana and it is safe not to remove the appendix. If one or more questions are answered with yes, it is advised to perform an appendectomy.

The five questions are:
1. Is there a perforation and/or necrosis?
2. Is the mesentery of the appendix thickened?
3. Is the appendix thickened?
4. Are the vessels on the serosa of the appendix injected?
5. Is there an adhesion around the appendix?

Study burden and risks

As it is a non-randomized study patients might already benefit from this study. The percentage of normal appendectomies is approximately 10-20% nowadays. The objective of the introduction of the LAPP score is to half this percentage. As the morbidity of a normal appendectomy is approximately 6%, patients might already benefit from the LAPP score. In our prospective cohort of 134 patients, use of the LAPP score would have led to no missed appendicitis and a normal appendectomy rate of 1% (N=1).
The lower incidence of normal appendectomies should not lead to an increase in missed appendicitis during the diagnostic laparoscopy. We feel that the missed appendicitis rate should be very low (< 1%).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients operated for the clinical suspicion of acute appendicitis that will undergo a diagnostic laparoscopy.
- Age * 18 years
- Written informed consent

Exclusion criteria

- Diagnostic laparoscopy and planned appendectomy for an appendectomy a froid.
- Primarily chosen for an open appendectomy.
- Not able to give informed consent (for example language barrier or legally incapable).
- Refused informed consent.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2013
Enrollment:	778
Type:	Actual

Ethics review

Approved WMO

Date:	23-07-2013
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL43820.042.13